



# ***Divi's Laboratories Limited***

Date.25<sup>th</sup> September 2017

To  
The Secretary  
**National Stock Exchange of India Limited**  
Exchange Plaza,  
Bandra-Kurla Complex, Bandra (East)  
**MUMBAI - 400 051**

To  
The Secretary  
**BSE Limited**  
Phiroze Jeejeebhoy Towers,  
Dalal Street  
**MUMBAI - 400 001**

**Stock Code: DIVISLAB**

**Stock Code: 532488**


Dear Sir/ Madam,

**Sub: Chairman Speech of 27<sup>th</sup> Annual General Meeting. - Reg.**

Further to our communication dated 25<sup>th</sup> September, 2017, please find attached herewith copy of Chairman's Speech delivered at the 27<sup>th</sup> Annual General Meeting (AGM) of the Company held on 25<sup>th</sup> September 2017 at 10.00 a.m. at Global Peace Auditorium, Brahma Kumaris, Shanti Sarovar, Academy for Better World, Gachibowli, Hyderabad - 500 032.

Thanking You,

Yours faithfully,  
For **Divi's Laboratories Limited**

  
P V Lakshmi Rajani  
Company Secretary



**“An ISO-9001, ISO-14001 and OHSAS-18001 Triple certified company”**

**Regd. Off. : Divi Towers, 1-72/23(P)/DIVIS/303, Cyber Hills, Gachibowli, Hyderabad - 500 032, Telangana, INDIA.**

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## Chairman's Speech

**Ladies and Gentlemen,**

Good Morning

On behalf of our Directors and myself, I extend a warm welcome to you all to this 27th Annual General Meeting of the company. Thank you for your presence here today, and for your continued support and goodwill that is critical to the success of our company.

The Annual Report for the year ended 31st March, 2017 along with notice of the meeting, Board's Report and the audited financial statements of the Company have been circulated to you. With your permission, I take them as read.

Before briefing on the highlights of performance during the year under review, I would like to share with you an update on the global pharma industry.

### Industry & Economic outlook

As per QuintilesIMS, global spending on medicines will reach nearly \$1.5 trillion in 2021 growing at about 4 to 7%. Over the last decade, the drivers of medicine spending and growth have shifted to pharmerging markets. However, the U.S. will continue to be the leading global market. Due to the ageing population worldwide, the requirement of medicines for these senior citizens will see increasing demand for both illness and wellness.

Divi's Labs continues to play a complementary role to its innovator Pharma customers and a non-conflict role to its generic customers and servicing them by supplying their requirements of custom synthesis and generic active pharma ingredients.

The evolving and changing cGMP regulatory compliances for access to advanced/value markets like Europe and USA has put a significant pressure on manufacturers to improvise and align their systems and protocols to be able to meet the changing regulatory compliance requirements. The recent inspections have impacted businesses of several large and small players in India which have exposure to the advanced markets. There is urgent need for the domestic pharma industry to overcome the deficiencies and ensure continuing compliance to the evolving regulatory requirements.

### Operations for the year

It is now my pleasure to brief you on Company's performance for the year :

During the year, our :

- ↑ Total Revenues for the year increased by 8% to Rs. 4142 crores.
- ↑ PBDIT for the year increased by 1% at Rs. 1514 crores.
- ↑ Profit before Tax (PBT) for the year increased by 1% to Rs.1388 crores.
- ↑ Profit after Tax (PAT) for the year was Rs.1053 crores.
- ↑ Earnings Per Share of Rs.2/- each came to Rs. 39.68 for the year as against Rs. 41.84 last year.
- ↑ Your Board recommends a dividend of Rs.10 per equity share of Rs.2 each (i.e., 500%), same as last year.

### Operations of Quarter ending 30<sup>th</sup> June, 2017

During the first quarter of the financial year 2017-18, we have achieved a total income of Rs. 851 crores as against an income of Rs. 1034 crores for the corresponding quarter of last year and Profit after Tax amounted to Rs.177 crores before Other Comprehensive Income.

Revenue for the quarter has been impacted due to the time required for setting up protocols and procedures for release of export shipments as stipulated in the Import Alert by the US-FDA. These have since been established and shipments for the exempted products are being done as per the protocols. In addition, there have been disruptions due to GST implementation and issues relating to this legislative landmark reform are getting normalized now.

### Regulatory Inspections

You are aware that the US-FDA has inspected our manufacturing site at Unit-II at Visakhapatnam during Nov-Dec, 2016 and has issued 5 observations in Form-483. Subsequently, during March, 2017, the FDA issued an Import alert under clauses 99-32 and 66-40. Along with the Import Alert, the US-FDA has also exempted several products from the Alert. We filed a detailed response to the observations in Form-483 issued by the FDA within the stipulated time, and as committed, we made further submissions in January and March, 2017. In May, 2017, the FDA issued a warning letter for the Unit-II. We filed a detailed response to the warning letter in time. Meanwhile, we have engaged external consultants, regulatory specialists and subject matter experts and have taken up appropriate remediation measures to address the concerns raised by US-FDA. During July, 2017, the US-FDA has lifted the Import Alert under Clause 99-32 based on our submissions. Besides updating these developments on the Stock Exchanges, we have also conducted a conference call with Investors, Analysts and Fund Managers on 27<sup>th</sup> March, 2017 and clarified on issues relating to this inspection.

During August, 2017, we had a successful inspection of our Unit-II jointly by the HPRA of Ireland and JAZMP of Slovenia, which are part of European Regulatory Agency.

Our Unit-II has again been inspected by US-FDA from 11<sup>th</sup> September to 19<sup>th</sup> September 2017. This inspection was for full cGMP and verification of all Corrective Actions proposed against the previous Inspection observations of December 2016. We are glad to report that all the previous observations have been confirmed as completed and resolved.

On completion of this inspection, the FDA has issued a Form-483 citing six observations which are procedural and the company will be responding to these within the stipulated time.

You are aware that North America and Europe account for a significant part of our business. North America constitutes 32% of our sales revenue and Europe accounts for about 43%. The company therefore devotes utmost importance for regulatory compliances for access to these markets and has been continuously upgrading its facilities, enhancing the Quality and Regulatory oversight and putting appropriate procedures and protocols in place to meet the cGMP requirements in order to comply with the regulations of these markets.

## Capex Plans

At the last Annual meeting, I have briefed about our capex plans for setting up a manufacturing facility on a green-field site at Ontimamidi Village near Kakinada, which is about 200 kilometers south of our Unit-II. Although the Government, through Andhra Pradesh Industrial Infrastructure Corporation (APIIC), allotted and gave us advance possession of the 505-acre site, APIIC could conclude registered sale agreements only for about 352 acres of land, in bits-and-pieces. Several farmers and earlier owners whose land had been acquired or resumed by the Government years ago, have now filed writ petitions before the Hon'ble High Court of Telangana and Andhra Pradesh contesting such acquisition/resumption or seeking additional compensation. Unless we are able to get a contiguous site, we will not be able to implement the Project. Meanwhile, we have secured the site, completed a public hearing and have applied for environmental and other clearances from the concerned Government Departments for setting up the manufacturing site for pharma ingredients.

The Company has spent an amount of Rs. 34 crores during the year for payment of the cost of land to the Government and securing the site. The company hopes that the Government would resolve the legal issue soon paving the way for handing over the rest of the land after which the company would be able to start setting up its manufacturing facility.

We have also obtained some approvals and permissions for the 83-acre site acquired near our Unit-II. Some of the locals have filed petitions before the National Green Tribunal which have been dismissed, but these persons have again filed review petitions. The company is in the process of resolving these issues.

In order to meet the immediate capacity requirements to cater to the visible business opportunities, we are creating capacities at the existing manufacturing sites and during the year, we have capitalized Plant, Property and Equipment (PPE) and Intangible Assets valuing Rs. 244 crores. In addition, an amount of Rs.444 crores spent on capex programs as of 31st March, 2017 is in Capital Work in Progress and would be capitalized during the year 2017-18. Our capex plans at the existing manufacturing sites also include building 2 additional production blocks at Unit-1 at an investment outlay of Rs.175 crores. This Capital expenditure at the existing Units will help us to meet the immediate capacity requirements.

## Regulatory Compliances

Divi's has been continuously upgrading its manufacturing facilities and reviewing its Quality and Regulatory systems and protocols to meet the cGMP regulations. Based on the regulatory requirements, the company has created new Process Support Centres at both the manufacturing sites. The company continuously augments and upgrade its facilities and research centres and has equipped them with modern instruments and process capabilities in order to handle a diverse portfolio and to meet global compliances.

In this direction, the company and its people are putting all efforts and energies through learning experiences, peer reviews as well as external consultants and overcome deficiencies to establish an enhanced compliance oversight mechanism.

## Environment, Health, Safety and CSR Initiatives

In pursuit of creating value, Divi's is conscious of optimum utilisation of resources and its commitment to green chemistry and the Environment. Utmost importance is given to orient our manufacturing and business processes towards this objective and also to ensure health & safety of our employees.

Our EHS Teams continuously monitor, review & update the procedures and protocols to ensure effective and efficient operations in order to mitigate risks or hazards. Process Safety Vigilance Team actively participates in continuous monitoring of the critical operations towards safe operations.

Divi's mission is to be a good corporate citizen and not only add value in our core competency area, but also serve the community at large through social, educational and environmental initiatives that would establish strong foundations for a better tomorrow.

From the very inception of its operations, Divi's has been taking up multiple programmes and developmental activities that benefited the communities or villages around the manufacturing sites in enhancing their quality of life and economic well-being. Our employees actively participate in these activities and wholeheartedly reach to those in need.

During the year, our Company has made significant contribution towards the welfare of underprivileged by providing infrastructure facilities, supporting education and extending scholarships to merit students and physically challenged. Divi's initiatives towards creation of sanitation facilities, safe drinking water, village and rural development around its manufacturing sites helped to improve livelihood of communities around. Details of the various programs taken up by the company are available in the Annual Report.

## Conclusion

Ladies and Gentlemen, on behalf of the Board, I would like to thank all our customers, suppliers, partners, associates for their support and contribution; and our employees for their trust and dedication. And I also thank M/s. PVRK Nageswara Rao & Co for their valuable contribution as auditors of the company for the last several years. We particularly thank you, our shareholders, for your steadfast faith and trust reposed in us.

## With warm regards

**Dr. Murali K. Divi**

Chairman & Managing Director

**Divi's Laboratories Limited**

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